REMARKS

Claims 1-28 are pending. Claims 1, 6, 7, 10, 11, 13, 22 and 28 are amended. New claim 29 is added. In the Office Action dated October 27, 2006, the United States Patent & Trademark Office (USPTO) rejected claims 3, 12, 14, 16-17 and 23 under 35 U.S.C. § 112, first paragraph and claims 1, 3, 12, 14, 16-17, 22-23 under 35 U.S.C. § 112, second paragraph. Applicant has amended claims 1 and 22 thereby overcoming the rejections and requests withdrawal of the rejections.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph. The USPTO contends that the Applicant's disclosure of "a plug" that includes "a layer of catalytic agent" not only converts nitrite/nitrate or nitrosothiols found in the blood but also converts nitrite/nitrate or nitrosothiols present in a bulk matrix/reservoir. The Applicant directs the Examiner's attention to paragraph 33, last sentence, "According to other embodiments, plug 79 includes catalytic layer 35 which is exposed to blood 37 via a plurality of pores included in layer 70." As such, at least one embodiment is described in the originally-filed application including a plug having a layer of catalytic agent that does not specify nitrite/nitrate or nitrosothiols present in a bulk matrix/reservoir. Applicant respectfully asserts that the rejection is improper and should be withdrawn.

Claims 1-4, 8-10, 12, 14, and 16-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes (U.S. 5,282,844) in view of Batchelor (U.S. 2002/0115559). Claim 1 is directed to an implantable therapy delivery and / or diagnostic device including "a fixation element adapted to secure the device to an implant site…one or more elongate conductors extending within the device…a polymeric layer overlaying a portion of the device in proximity to the implant site and including an outer surface…an electrode positioned along the polymeric layer and comprising multiple coil turns and a layer of a catalytic agent, having nitrite reductase and / or nitrate reductase, or nitrosothiol reductase activity,

present on the outer surface of the polymeric layer and being exposed between the coil turns." Stokes relates to an implantable medical lead but does not describe an electrode positioned along the polymeric layer and comprising multiple coil turns and a layer of a catalytic agent being exposed between the coil turns. The USPTO concedes that Stokes does not include a layer of catalytic agent. The USPTO relies upon the teachings of Batchelor relating to a biocompatible material having a layer of a catalytic agent having nitrite reductase activity. Batchelor indicates the material may be cast or otherwise shaped to comprise a monolithic device, such as implantable device such as drug depot or in-dwelling devices such as catheters or extracorporeal tubing sets. The material may also be applied as a film on another substrate that may be a polymer or a metal device such as arterial stents, guide wires, catheters, bone anchors and screws, …electrical leads, biosensors, and probes. However, even when combined, Stokes and Batchelor fail to teach, suggest or imply a layer of a catalytic agent being exposed between the coil turns of an electrode. As such, Applicant requests withdrawal of the rejection.

Claim 27 is directed to an implantable therapy delivery and / or diagnostic device including a body including a sidewall having a plurality of pores …a plug held within the porous sidewall and including a layer of catalytic agent, having nitrite reductase and / or nitrate reductase, or nitrosothiol reductase activity present on an outer surface of the plug wherein the catalytic layer, exposed to blood through the plurality of pores, converts nitrite/nitrate or nitrosothiols only in the blood to nitric oxide. Stokes describes a polymeric plug within an electrode. The plug is impregnated with a water soluble form of glucocorticosteroids. Since Stokes' plug is an impregnated plug within an electrode, Stokes fails to teach or suggest a plug having a layer of a catalytic agent held within the porous sidewall of a device body. While Batchelor teaches a material having a catalytic agent Batchelor fails to remedy the deficiency of Stokes. As such, Applicant respectfully asserts the rejection is improper and should be withdrawn. If the

USPTO continues to reject the claim, Applicant requests the Examiner address claim 27 as a whole.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes in view of Batchelor and further in view of Halperin (U.S. 5,564,434). Halperin fails to remedy the deficiency noted with Stokes and Batchelor as described above.

Claims 1-6, 8-10, 12, 14, 19-21 and 28 are rejected under 35 U.S.C. § 103(a) based upon Borgersen (U.S. 2001/0018607) in view of Batchelor. Claims 7, 11, and 13 are also rejected under 35 U.S.C. § 103(a) based upon Borgersen in view of Batchelor and Vachon (U.S. 5,861,023). Borgersen discloses a multi-lumen medical lead that includes a conventional defibrillation electrode. Borgersen makes no suggestion of a catalytic layer exposed between electrode coil turns. For the same or similar reasoning as discussed above, Batchelor fails to remedy this deficiency of Borgersen. Vachon discloses a lead having a coil electrode overlayed with a sulfonated thermoplastic. The cited references, even when combined, fail to teach, suggest or imply a layer of a catalytic agent being exposed between electrode turns. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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